REMARKS

Claims 1-4 and 6 are canceled. Claims 5 and 12 are amended. Claims 7 and 20-25 are withdrawn from consideration by the examiner. Hence, claims 5 and 8-19 remain active and under consideration in this case.

Claims 5, 6 and 8-18 stand rejected under 35 USC 102(b) as being anticipated by Hudson et al. (WO 02/064634 A2, of record).

However, this reference would have clearly neither disclosed nor suggested the claimed invention to one of ordinary skill in the art at the time it was made.

In particular, Hudson et al. merely disclose antibodies which bind FcαRI, and fragments of these antibodies, including monovalent fragments. These antibodies and fragments thereof are used for preparing bifunctional reagents containing a binding region directed against the FcαR of an effector cell, and a binding region directed against a target antigen.

Hudson et al. disclose the use of these bifunctional reagents to treat various diseases, including inflammatory or allergic diseases such as asthma. The binding of the bifunctional antibody having a binding region directed against the FcαR and a binding region directed against IgE links an effector cell expressing FcαR to a target cell expressing IgE, resulting in the lysis of the target cell. Clearly, this reference fails to either disclose or suggest any therapeutic method involving the use of an

anti-inflammatory agent consisting of a monovalent antigen-binding fragment.

Hence, the product used in the claimed method and the prior art product are not, in fact, "identical or substantially identical in structure or composition." See page 6 of the Official Action.

Thus *In re Best* and *In re Spada* are clearly inapplicable in this case. Hence, this ground of rejection is deemed to unsustainable and should be withdrawn.

Claims 5, 6 and 8-19 stand rejected under 35 USC 102(b) as being anticipated by Shen et al. (US 6,018,031, of record).

However, this reference would have clearly neither disclosed nor suggested the claimed invention to one of ordinary skill in the art at the time it was made.

Notably, this reference merely discloses (in the same manner as Hudson et al.) antibodies which bind FcαRI, and fragments thereof, their use in preparing bifunctional reagents, and various therapeutic methods involving the administration of these bifunctional reagents for directing an effector cell expressing FcαR to a target antigen. Also, this reference (like Hudson et al.) neither discloses nor suggests the administration of a monovalent antibody fragment in itself, nor the selection of a fragment directed against the EC2 domain of the FcαRI receptor.

Moreover, *In re Best* and *In re Spada* are believed to be inapplicable for the same reason noted above.

Clearly, one skilled in the art would have been neither motivated nor enabled by either Hudson et al. or Shen et al. to arrive at the claimed method. Specifically, one of ordinary skill in the art would have been neither motivated nor enabled from either cited reference, alone or in combination, to use an anti-inflammatory agent consisting of a monovalent antigen-binding fragment in a therapeutic method of treating an inflammatory disease in a mammal. This is even more true since the monovalent antigen-binding fragment of the antibody is directed against the EC2 domain of the FcαRI receptor.

Hence, this ground of rejection is believed to be unsustainable and should be withdrawn.

Claims 5, 6 and 8-19 stand rejected under 35 USC 102(b) as being anticipated by van de Winkel et al. (WO 99/41285, of record).

However, this reference would have neither disclosed nor suggested the claimed invention to one of ordinary skill in the art at the time it was made.

In particular, this reference merely discloses macrophage-binding compounds which contain a first portion that binds to an Fc receptor present on a macrophage, and a second portion which is a cytotoxic agent. The first portion allows the binding of the compound to the macrophages, which are then killed by the cytotoxic agent. These macrophage-binding compounds can be used in the treatment of a variety of diseases involving macrophages, including asthma. However, this reference clearly fails to either disclose or suggest the use of a monovalent antibody fragment not bound to a cytotoxic agent.

Clearly, one of ordinary skill in the art would have been neither motivated nor enabled from this reference to arrive at the claimed method. Notably, the artisan would have had no motivation to use a monovalent antibody fragment not bound to a cytotoxic agent in any therapeutic method whatsoever. Further, the artisan would have been neither motivated nor enabled to use a monovalent antigen-binding fragment of an antibody directed against the EC2 domain of the FcαRI receptor.

Moreover, *In re Best* and *In re Spada* are believed to be inapplicable for the same reason noted above. Hence, this ground of rejection is believed to be unsustainable and should be withdrawn.

Claim 19 stands rejected under 35 USC 112, first paragraph, as ostensibly failing to comply with the "enablement requirement." However, this ground of rejection is respectfully traversed for the reasons noted below.

Notably, IgG1k antibody A77 (hereinafter 'A77') was known for several years prior to the date the claimed invention was made. As evidence of this, attention is directed to U.S. patents 5,922,845 and 6,682,928. Specifically, claim 13 of the '845 patent recites a bispecific molecule containing an antigen binding fragment of A77. Claims 15,16, 18 and 22 of the '928 patent recite a cell and a vector containing a fragment of A77. Both disclosures make it clear that antibody A77 was known even before the filing date of these two patents. Hence, it is clear that antibody A77 was both readily known and available to the public before the date the claimed invention was made. Copies of these two U.S. patents is not provided with this response as the same are presumed to be readily available to the examiner.

Hence, this ground of rejection is deemed to be moot and should be withdrawn.

Claim 12 stands rejected under 35 USC 112, first paragraph.

However, in view of the above amendment of claim 12, this ground of rejection is deemed to be moot.

Furthermore, attached to this response is a copy of a publication (Kanamaru et al., J. Immunol., pp. 2679-2678 (2008) that evidences that the claimed method would be useful not only for treating asthma, but also for treating other inflammatory conditions. Specifically, this publication describes subsequent studies conducted by the inventors' team, which confirm the anti-inflammatory properties *in vivo* of the monovalent antibody fragments of the present invention by showing a reduction of renal inflammation in a model of immune-mediated glomerulonephritis as well as in a model of nonimmune-mediated nephritis.

In view of this evidence, it is clear that treatment of inflammatory conditions other than asthma is enabled by the present specification.

Finally, claim 5 stands objected to for the reason noted at page 9, paragraph 9 of the Office Action.

In view of the amendment to claim 5, this ground of rejection is deemed to be moot.

Accordingly, in view of all of the claim amendments, accompanying remarks and copy of the *Kanamaru et al.* publication, it is believed that this application now stands in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

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